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EXAMINER

HARVEY, DIONNE

ART UNIT PAPER NUMBER

2643

DATE MAILED: 06/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/023,279

Applicant(s)

Rubinstein

Examiner

Dionne Harvey

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Drawings

1. The drawings are objected to because prior art figure 15 is not provided in the illustrated drawings. A proposed drawing correction or corrected drawings are required in reply to the Office action.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 14 recites "...receiving through applying." This is indefinite and correction is required.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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2. Claims 1-8, 11-13, 16 and 18-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Loeb (US 5,571,148).

Regarding claims 1 and 22,

Loeb teaches a signal generator (66) that generates a second signal (primary signal f_0 is divided by divider circuit 86 so as to produce a carrier frequency f_n which is then converted to a power signal by the power driver circuit 88) causing pseudospontaneous activity (see col 1, ln 27 through col 2, ln 14 wherein Loeb teaches the generation of the electric signal that would otherwise be generated by the hair cells of a profoundly deaf person, allowing the person to experience the sensation of hearing; also see column 4, ln 5-6 and column 11, ln 28 wherein Loeb teaches the production of a stimulation pulse); a transducer means(70); a signal processor 60 (which is better illustrated in figure 6) that combines a first signal that represents sound (address control logic 82 generates an address/control word which represents the audio signal 74 transmitted by audio sensor 70) and the second signal (see the power/carrier signal generated by power driver 88) to output a combined signal (the power signal and data signal are combined in the modulator 89 and transmitted via external coil 56); and a stimulation unit (see figure 4a which illustrates micro stimulator 20a). In col 1, ln 27 through col 2, ln 14, Loeb further teaches providing a nerve-to-brain link which generates the electric signal that would otherwise be generated by the hair cells of a profoundly deaf person, allowing the person to experience the sensation of hearing.

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Regarding claim 2,

In column 10, lines 25-27, Loeb teaches that the stimulation unit is an electrode array(36) coupled to the auditory nerve.

Regarding claims 3 and 23,

Loeb teaches that the first signal (see the Address/Control Word) is applied to a subset of electrodes (see column 12, lines 22-25) in the electrode array, and the second signal(modulated power signal) is applied to a second subset of electrodes in the electrode array(see column 11, lines 24-31).

Regarding claim 4,

Loeb teaches that the second signal is at a frequency above *approximately* 2k HZ, as broadly claimed.

Regarding claims 5,6 and 25,

Loeb teaches pseudospontaneous activity in a plurality of nerve fibers in the auditory canal (see col 1, ln 27 through col 2, ln 14).

Regarding claim 7,

Shown in Figure 6, Loeb teaches summing the first and second signals (see modulator 89), as broadly claimed.

Regarding claim 8,

Shown in Figure 4A, Loeb teaches a microphone(70) that generates a first signal, the microphone being coupled to the signal processor(60).

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Regarding claim 11,

The method of claim 11 is rejected for the same reasons set forth in the rejection of claims 1 and 22 as being inherently taught by the apparatus of claims 1 and 22.

Regarding claim 12,

Loeb teaches that the combined signal is applied to the auditory nerve(column 10, lines 25-27) and the first signal is received from the signal processor(60).

Regarding claim 13,

Loeb teaches that the first signal represents at least one of speech, emergency signals and control information.

Regarding claim 14,

Loeb teaches an inner implant capable of performing the steps of receiving through applying, as broadly claimed.

Regarding claim 16,

Loeb teaches an auditory prosthesis adapted to stimulate the auditory nerve comprising: pseudospontaneous generation means (see column 1, line 55 through column 2, line 14); a transducer means(70), a pseudospontaneous driving signal (see output of power driver circuit 88); and stimulation means (20a) operatively coupled (30,56) to the electrical input signals generated by the transducer means signal generator wherein at least one of a plurality of electrical signals is capable of causing activity in a plurality of nerve fibers of an auditory nerve (see col 1, ln 27 through col 2, ln 14 wherein Loeb teaches the generation of the electric signal that would

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otherwise be generated by the hair cells of a profoundly deaf person, allowing the person to experience the sensation of hearing).

Regarding claims 18 and 21,

Loeb teaches that the second signal is at a frequency above *approximately* 2k HZ, as broadly claimed.

Regarding claim 19,

It appears that Loeb teaches that applying the combined signal generates substantially continuous activity, thus permitting the sensation of hearing as disclosed in column 2.

Regarding claim 20,

Loeb teaches that the second signal is not continuously applied.

Regarding claim 24,

It appears that Loeb teaches that the electrical stimulation causes statistically independent activity in a plurality of nerve fibers in the auditory nerve, as discussed in column 2.

Regarding claim 26,

Loeb teaches that the second signal is at a frequency above *approximately* 2k HZ, as broadly claimed.

Regarding claim 27,

Loeb teaches that the prosthesis is a cochlear implant applying current to the auditory nerve.

Regarding claim 28,

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It appears that Loeb teaches that the pseudospontaneous activity continues after the second signal has stopped, thus permitting the sensation of hearing as disclosed in column 2.

Regarding claim 29,

The method of claim 29 is rejected for the same reasons set forth in the rejection of claim 16 as being inherently taught by the apparatus of claim 16.

Regarding claim 30,

Loeb teaches that the second signal is at a frequency above *approximately* 2k HZ, as broadly claimed.

Regarding claim 31,

Loeb teaches that the prosthesis is a cochlear implant applying current to the auditory nerve.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 9,10,15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loeb (US 5,571,148).

Regarding claims 9,15 and 17, Loeb fails to teach that the signals are combined by adding, multiplying or an AND operator. However, the Examiner takes the Official Notice that

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the use of such operators when summing signals is well known in the art and it would be obvious to one of ordinary skill in the art at the time of the invention to employ any one of a number of combining methods to transmit a plurality of signals.

Regarding claim 10, Loeb teaches a microphone(70); signal processor(60); signal generator(66) and stimulation unit(45,36) coupled to the auditory nerve via cochlea. Loeb fails to specifically teach coupling between the stimulation unit and signal processor via wire. However, as disclosed in column 9, lines 47-58, Loeb teaches that "...several available coupling techniques may be used" for coupling information between the processor and the implanted stimulator . Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to employ any one of a variety of coupling techniques disclosed by Loeb to transmit information to the implanted stimulators.

Response to Arguments

4. Regarding the Applicant's argument that Loeb Fails to Disclose a Second Signal Capable of Causing Pseudospontaneous Activity in the Auditory Nerve:

In page 14 of the Applicant's specification, "pseudospontaneous activity" is defined as "...artificially induced random pattern of activation of the auditory nerve..." In columns 1 and 2, Loeb first discloses a recognized need in the art for electrically stimulating the auditory nerve of a profoundly deaf person via the application of electrical pulses in the cochlea. Loeb goes on to teach that Fibers of the auditory nerve originate in the nerve cell which contacts hair cells.

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Incoming sound waves cause movement in the cilia of hair cells thus causing the hair cells to induce electrical pulses in the auditory nerve. The profoundly deaf person is unable to generate these electrical signals or random patterns. Loeb's invention is primarily concerned with the generation of electrical signals or random patterns to stimulate the auditory nerve which would otherwise be generated by the hair cells of the profoundly deaf. For these reasons, it is the Examiner's opinion that the disclosure of Loeb anticipates the limitation of the claims, specifically with respect to the generation of "pseudospontaneous activity".

5. Regarding the Applicant's argument that Loeb Fails to Teach That the Transmitted Signals Are in a High Enough Frequency Range So as to Result in Pseudospontaneous Activity:

The Applicant has failed to specifically claim the frequency range for transmission of the carrier and/or data signal as argued. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Since the specific frequency range for signal transmission is not recited in the rejected claim(s) thus distinguishing the invention from the art of record, the rejection is maintained.

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statements for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dionne Harvey whose telephone number is (703) 305-1111. The examiner can normally be reached on Monday through Friday from 8:30am to 6:00pm.

Any responses to this action should be mailed to:

Commissioner of Patents and Trademarks

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Washington, DC 20231

or faxed to:

(703) 308-6306, for formal communications for entry

Or:


(703) 308-6296, for informal or draft communications, please label "PROPOSED" or "DRAFT".

Hand delivered responses should be brought to Crystal Park II, 2121 Crystal Drive,
Arlington, VA., Sixth Floor(Receptionist)

If attempts to reach the examiner by telephone are unsuccessful, the examiner's
supervisor, Curtis Kuntz, can be reached at (703) 305-4708.

Any inquiry concerning this communication or earlier communications from the
examiner should be directed to Dionne Harvey whose telephone number is (703) 305-1111.

D.H.


CURTIS KUNTZ
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